

K113300

Special 510(K) Premarket Notification
PTA Balloon Catheter: ATB Advance® PTA Dilatation Catheter
Cook Incorporated
4 November 2011

DEC - 9 2011

510(k) Summary

Submitted By:

Elysia Poor
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
812-339-2235

Device:

Trade Name: ATB Advance® PTA Dilatation Catheter

Proposed Classification: Catheter, Percutaneous
(74 DQY)

Indications for Use:

For percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and iliofemoral as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The ATB Advance® PTA Dilatation Catheter is also intended for post dilatation of balloon-expandable peripheral vascular stents.

Predicate Devices:

ATB Advance® PTA Dilatation Catheter cleared under the following 510(k) Premarket Notifications:

- D.C.#K033875, April 2, 2004
- D.C.#K052036, August 25, 2005
- D.C.#K063252, November 14, 2006

Device Description:

The ATB Advance® PTA Dilatation Catheter is an over-the-wire catheter indicated for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and iliofemoral as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The ATB Advance® PTA Dilatation Catheter is also intended for post dilatation of balloon-expandable peripheral vascular stents. The 6 Fr balloon catheter will be compatible with a 0.035 inch wire guide and an 8 Fr sheath. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

Cook currently markets the PTA Balloon Catheter which is considered substantially equivalent to the ATB Advance® PTA Dilatation Catheter. The identical indications for use and technological characteristics of the ATB Advance® PTA Dilatation Catheter as compared to the predicate device support a determination of substantial equivalency. The ATB Advance® PTA Dilatation Catheter has

been modified from the predicate ATB Advance® PTA Dilatation Catheter to include a balloon size combination of 14 mm diameter x 2 cm length.

Test Data:

The ATB Advance® PTA Dilatation Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Balloon Minimum Burst Strength – Testing shows the balloons will burst at or above the minimum rated burst pressure, with all failure modes being linear tears. Predetermined acceptance criteria met.
2. Balloon Compliance – Testing shows that, under simulated body temperature conditions, each balloon will meet its labeled diameter within tolerance at the nominal pressure. Predetermined acceptance criteria met.
3. Balloon Profile – Measurement of the diameter of catheter shaft, bonds, and folded balloon shows that the device is compatible with an 8 Fr sheath (< 0.113 inch profile). Predetermined acceptance criteria met.
4. Balloon Fatigue – Testing shows that balloons are free from leakage and damage on inflation, withstanding 10 cycles of inflation/deflation (inflating to rated burst pressure, holding for 30 seconds and deflating). Predetermined acceptance criteria met.
5. Sheath Compatibility – Qualitative and quantitative evaluations show that the balloons are compatible with an 8 Fr sheath. Predetermined acceptance criteria met.
6. Balloon Bond Strength – Testing shows the tensile force during proper clinical use should not fracture or rupture the balloon catheter bond. In conformance with the applicable sections of ISO 10555-1: 1995, predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and effective as the predicate device and support a determination of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2011

Cook, Inc.
c/o Ms. Elysia Poor
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K113300

Trade/Device Name: ATB Advance PTA Dilatation Catheter

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous catheter

Regulatory Class: Class II (two)

Product Code: LIT, DQY

Dated: November 4, 2011

Received: November 9, 2011

Dear Ms. Poor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure.

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PTA Balloon Catheter: ATB Advance® PTA Dilatation Catheter
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Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Williams
(Division Sign-Off)
Division of Cardiovascular Devices

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